



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,067	09/16/2003	Seth T. Rodgers	B1102.70029US00	3250

7590 02/04/2008
Timothy J. Oyer, Ph.D.
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
----------	--------------

1797

MAIL DATE	DELIVERY MODE
-----------	---------------

02/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,067	Applicant(s) RODGERS ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45, 47-54 and 120-166 is/are pending in the application.
- 4a) Of the above claim(s) 120-166 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45 and 47-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>071907</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 120-166 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: the invention as originally claimed pertains to a method of producing a chip, whereas the newly submitted claims pertain to either an apparatus, a system, or a method for screening a plurality of test compounds.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 120-166 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 45, 49, 53 and 54 are rejected under 35 U.S.C. 102(b) as being unpatentable over Thomas (WO 9955827) in view of Freeman (US 6653124).

With respect to claim 45, Thomas discloses a method of producing a device comprising a predetermined reaction site (Figure 1:2). The reaction site is formed by attaching a first component of the device to a second component of the device with or without auxiliary adhesives. Page 2, line 25 to page 3, line 6, page 5, lines 6-11 and page 6, lines 10-22 indicate that microchannels and microchambers are formed by adhering a cover plate to a micro-machined substrate. Page 11, lines 21-24 and page 18, lines 4-6 state that the reaction site is roughly circular in shape and characterized by a diameter of 400-600 microns. Therefore, Thomas's bioreactor vessels are about 0.1 microliters in volume. Thomas, however, does not expressly indicate that a membrane having a pore size less than 2.0 microns is attached to the chip.

Freeman discloses a method for producing a microfluidic cell culture chamber on a chip that comprises using a nanoporous semipermeable membrane (Figure 3:40) to selectively deliver oxygen, nutrients, and reagents to growing cells. This is disclosed in column 24, line 56 to column 25, line 2. Since Freeman teaches in column 25, lines 42-45 that the covers (Figure 3:50, 52) surrounding the cell culture chamber are transparent to light to facilitate the detection of events within the chamber, it likewise would have been obvious to ensure that the semipermeable membrane disclosed by Freeman is transparent as well. Transparent membrane materials are considered to be well known in the art.

Thomas and Freeman are analogous art because they are from the same field of endeavor regarding microfluidic cell culture chambers.

At the time of the invention, it would have been obvious to alter the method of chip production disclosed by Thomas in order to incorporate a nanoporous membrane in the cell culture area. Freeman teaches in column 24, line 56 to column 25, line 2 that membranes are beneficial because the pore size can be selected to facilitate the diffusion of a desired metabolite into the cell culture area. Freeman specifically indicates that membranes are useful in selectively delivering oxygen and nutrients to cells to encourage growth.

With respect to claim 49, Thomas and Freeman disclose the method set forth in claim 45 as set forth in the 35 U.S.C. 103 rejection above. Thomas additionally indicates that the first component comprises polystyrene and polycarbonate polymers. This is described on page 7, lines 8-15.

With respect to claims 53 and 54, Thomas and Freeman disclose the method set forth in claim 45 as set forth in the 35 U.S.C. 103 rejection above. Thomas additionally states that the first component is attached to the second component to produce an enclosed, liquid-tight junction therebetween. This is described on page 2, line 25 to page 3, line 6, page 5, lines 6-11 and page 6, lines 10-22.

2) Claims 47, 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (WO 9955827) in view of Freeman (US 6653124) as applied to claim 45, and further in view of Kellogg (US 20040259237) and/or Wilding (US 6184029).

Thomas and Freeman disclose the method set forth in claim 45 as set forth in the 35 U.S.C. 103 rejections above, however does not expressly disclose by what process the first component is attached to the second component.

Kellogg discloses a microfluidic system for isolating and amplifying nucleic acids derived from cell cultures. Kellogg states in paragraph [0162] that the biochemical system is formed by attaching a microfluidics disc (Figure 1:201) to a sealing layer (Figure 1:301). Paragraph [0107] teaches that attachment is achieved by applying heat energy to melt at least a portion of the first component.

Wilding discloses a microfluidic detection system that comprises a first component (Figure 1:11) attached to a second component (Figure 1:29). A plurality of a sealed microchannels and microchambers are formed through the attachment of the first component to the second component. Wilding teaches in column 8, lines 38-53 that the first component is attached to the second component using ultrasonic welding.

Thomas, Freeman, Kellogg and Wilding are analogous art because they are from the same field of endeavor regarding the construction of microfluidic systems.

At the time of the invention, it would have been obvious to ensure that the first component and second component of Thomas are attached to each other using a technique such as sonic welding and heat pressing. As evidenced by Kellogg and Wilding, these processes are well known in the art, and are effective in sealing layers together in microfluidic systems. It would have been apparent to one of ordinary skill in the art to adhere the first and second components disclosed by Thomas to each other using any procedure known in the microfluidic chip art.

Response to Arguments

Applicant's arguments filed 01 November 2007 with respect to the 35 U.S.C. 102 rejections involving Thomas have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Thomas and Freeman.

Freeman addresses the deficiencies of Thomas by indicating that it is known in the art to construct a cell culture chamber by using a membrane to regulate the diffusion of desired metabolites.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

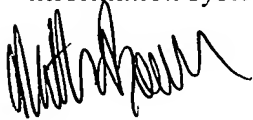
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/664,067
Art Unit: 1797

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NAB



GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER